EXHIBIT U

AMERICAN SOCIETY OF CLINICAL ONCOLOGY COMMENTS ON THE PROPOSED RULES TO IMPLEMENT THE PHYSICIAN FEE SCHEDULE

These comments are submitted by the American Society of Clinical Oncology (ASCO), the national professional medical organization representing physicians who specialize in the treatment of cancer.

CONVERSION FACTOR

We agree with the rest of organized medicine that the proposed calculation of the conversion factor is unfair and should be revised. HCFA should not reduce the conversion factor based on the unproven assumption that physicians will increase the volume of their services to offset payment reductions. In addition, HCFA should not reduce the conversion factor to account for the supposed effect of the transition provisions. The combined effect of these adjustments is to reduce the conversion factor by 16 percent in the first year and to establish a lower base for future years' updates.

This major unwarranted reduction of Medicare payments will thwart a principal intended purpose of the fee schedule, which is to significantly increase Medicare payments to non-procedural specialties like medical oncology. ASCO urges HCFA to adopt a conversion factor that does not include any reduction based on assumptions about changes in physician behavior or on the effect of the transition provisions.

PAYMENT FOR DRUGS

Under the proposed rules, Medicare payment for drugs would be reduced to 85 percent of average wholesale price (AWP), or even lower in the case of "high volume" or "high cost" drugs where HCFA estimates a lower acquisition cost. ASCO strongly objects to this proposal.

A. Background

1. The HCFA Proposal

The drugs subject to this proposal are largely injectable drugs administered in physician offices. ASCO is the specialty society most concerned with this proposal, since many of the drugs covered by Medicare in this situation are related to the treatment of cancer. Moreover, medical oncologists are especially affected since chemotherapy is their primary treatment modality.

Oncologists and other physicians who administer drugs in their offices purchase the drugs from wholesalers, and in some cases directly from manufacturers, hold the drugs in inventory in their offices, and take the drugs from the inventory as they are needed for their patients. This practice differs, of course, from the procedure for most drugs, where the physician writes a prescription that is filled at a pharmacy from the pharmacy's inventory.

Although drugs covered by Medicare are by statute subject to payment on a reasonable-charge basis, the Medicare Carriers Manual directs carriers to limit payment to an amount based on estimated acquisition cost. The estimated acquisition cost is based on a published listing of

AWP, such as in the Drug Topics Red Book. Most carriers pay AWP, while a few pay AWP plus or minus a percentage factor.

Under the proposal, a uniform payment formula would be established at 85 percent of AWP.[1/] In addition, HCFA could, solely through carrier instructions, identify the estimated acquisition cost of "high volume" or "high cost" drugs, and set Medicare payment at the lower of that amount or 85 percent of AWP.

The proposal is based on the results of surveys by the Office of Inspector General (OIG) of the prices paid by pharmacies for drugs. In a 1984 study, OIG determined the prices paid by a sample of pharmacies in six states for a sample of 36 drugs. It found that the pharmacies paid an average of 15.9 percent less than AWP. In its 1989 study, OIG determined the prices paid by pharmacies for 55 high volume drugs, based largely on the prices of a single national wholesaler, and supplemented by price information obtained from certain Arkansas and Louisiana pharmacies. The 1989 study showed the average price of single-source drugs to be 14.4 percent less than AWP, and the average price of multiple-source drugs to be 18.2 percent less than AWP.

2. The Drug Market

The use of any across-the-board rule designed to cover the costs incurred by physicians in acquiring drugs is made very difficult by the enormous variation in prices paid. Surveys, like that of the OIG, that focus on average price obscure the range of prices actually paid. Although there is little definitive information available, some general statements can be made about the characteristics of the market.

Drug manufacturers sell their products to drug wholesalers, who in turn sell them to physicians, pharmacies, and hospitals. Manufacturers also typically sell their products directly to physicians, although there may be restrictions (for example, minimum quantities) that a physician must satisfy before such a direct sale would be made.

The manufacturer's price for sales to wholesalers is, of course, less than the published AWP. Manufacturers will sometimes sell to physicians at the same price as to wholesalers, but often the price to physicians is higher to account for the higher transaction costs of dealing with smaller amounts of product.

1/ We note an apparent discrepancy between the proposal as discussed in the preamble and the text of the proposed regulation. The preamble refers to the published average wholesale price, whereas the proposed regulation (§ 415.34) refers to the "national average wholesale price of the drug as determined by HCFA." Since the underlying rationale of the proposal is that AWP as published in sources such as the Red Book does not reflect the true price, any reference in the regulation must be to published AWP. Insofar as the regulation text suggests that HCFA could determine true average wholesale price and then pay only 85 percent of that, it plainly is inconsistent with the rationale of the rule.

Wholesalers mark up the prices of the products by varying amounts. Some oncologists find that they must pay the full published AWP for certain drugs. More frequently, the wholesale price to oncologists is somewhere between what the wholesaler paid to the manufacturer and the full AWP. Informal surveys indicate that there is little national consistency in the amount of the mark-up for drugs used by oncologists, but rather that there is substantial variation.

There is also a significant difference between pricing for single-source and for multiple-source drugs, as suggested by the 1989 OIG survey. Manufacturers of single-source drugs seem rarely to offer discounts from their list prices. Accordingly, price variation depends on the amount of mark-up taken by wholesalers. Manufacturers of multiple-source drugs, however, seem to offer discounts more frequently. Thus, price variation for these drugs depends both on the manufacturer's price and on the wholesale mark-up.

A noteworthy fact about pricing practices for drugs is that the same price is not available uniformly to all physicians at all times. It appears, not surprisingly, that physicians in larger practices that are able to order large quantities of drugs are more frequently able to obtain lower prices than are physicians in small practices. Prices also vary greatly through time. Many discounted prices are offered only for limited periods of time or under special circumstances.

Although oncologists who are allowed to purchase directly from a manufacturer would ordinarily pay a lower price to the manufacturer than to a wholesaler, many if not most oncologists find that the additional costs of dealing with multiple manufacturers outweigh the savings available. One major manufacturer of oncology drugs has advised ASCO that about 60 percent of its products used by physicians are distributed through wholesaler channels, rather than sold directly to oncologists, presumably because oncologists wish to avoid the extra costs of purchasing directly from manufacturers. Thus, in light of the significant additional administrative costs incurred in purchasing directly from manufacturers, HCFA should not assume that prices available for purchases from manufacturers should be used in determining appropriate payment levels.

The upshot of these facts is that surveys of a sample of physicians, or of prices paid at a particular time, or of average prices may not accurately reveal the degree of variation in prices paid by individual oncologists. As discussed below, since HCFA's policy is to cover the drug costs incurred by physicians, it is important that the policy cover the drug costs of every physician in all circumstances, not simply the average physician or usual situations.

B. Legal Defects in the Proposed Rule

The proposed rule is inconsistent with both substantive and procedural requirements applicable to payment limitations.

1. Substantive Legal Standard

The proposed payment restrictions are based on HCFA's authority under section 1842(b)(8) of the Social Security Act to deviate from the ordinary reasonable charge methodology. That provision authorizes Medicare, in the case of "particular items or services,"

to establish "realistic and equitable" charges if the usual mechanisms for determining reasonable charges result in "grossly excessive" charges that are not "inherently reasonable." The provision requires HCFA to issue regulations that set out the factors to be used in these determinations.

While the statute and accompanying regulations do not extensively address how HCFA is to determine the initial issue of whether charges are "grossly excessive," the regulations set out several circumstances which "may result in grossly ... excessive charges," including where "charges are grossly ... in excess of acquisition or production costs." 42 C.F.R. § 405.520(g)(1). The preamble to the proposed rule on drug payments cites this provision as authority for the proposed limits.

HCFA is authorized to limit payments for drugs only if these standards are satisfied. These standards do not authorize HCFA simply to limit payment to the estimated acquisition cost. Rather, under the statute and regulations, limitations can be imposed only if payments are "grossly" in excess of acquisition costs. This standard plainly allows for Medicare payments to exceed acquisition costs by a significant amount, so long as the amount is not grossly excessive, and HCFA lacks authority to reduce payment amounts to equal the acquisition costs.

Moreover, any limits imposed must be "realistic and equitable." As we demonstrate below, there are numerous considerations that are properly taken into account in addition to the acquisition cost of the drug itself but that have not been incorporated into the proposed limits.

2. Procedural Requirements

In addition to the proposal's failure to meet the substantive standards for payment limits, there are two serious procedural defects in the proposal.

First, the proposed use of price data for a sample of drugs to establish an across-the-board rule for all drugs is inconsistent with the statute. Section 1842(b)(8) of the Act permits HCFA to deviate from the reasonable charge methodology only for "particular items or services" when the reasonable charge methodology results in charges that are grossly excessive. Each covered drug is a different item and has a different HCFA Common Procedure Coding System (HCPCS) code. Even if HCFA establishes that the usual reasonable-charge methodology results in grossly excessive charges for a particular drug, that fact is not justification under the statute for applying the limitation to other drugs.

We do not regard this point as hypertechnical, but rather one that goes to the heart of our concern with the proposed rule. It is true that some drugs can be purchased by some physicians at prices below AWP. But, as pointed out above, prices are not uniform for all physicians at all times. Survey data, such as that of the OIG, are applicable only to the drugs, individuals, and times surveyed. Survey information on some drugs cannot properly be extrapolated to other drugs as HCFA is proposing to do.

Second, we take exception to the proposal to establish lower payment rates for unspecified "high cost" or "high volume" drugs through informal issuances to carriers. The essence of this

proposal is that HCFA would identify drugs for which the estimated acquisition cost is less than 85 percent of AWP, and would announce that estimated acquisition cost informally.

This proposal is inconsistent with the rulemaking requirements of the Administrative Procedure Act (5 U.S.C. § 553), as well as with the comparable provisions of the Medicare statute. Under section 1871(a)(2) of the Social Security Act, "[n]o rule [or] requirement ... that establishes or changes a substantive legal standard governing ... the payment for services ... shall take effect unless it is promulgated by the Secretary by regulation ...." Under this provision, HCFA lacks authority to reduce payment for a drug simply by announcing a purported estimated acquisition cost that is less than 85 percent of AWP.

Implementation of this proposal would depend critically on what HCFA estimates to be the acquisition cost of each affected drug. As noted above, there is no uniform acquisition cost amount that HCFA could simply ascertain and act upon. Instead, any amount used by HCFA would be an average or otherwise represent only a portion of the acquisition costs actually being incurred. Any estimate will inevitably be subject to question. Such estimates must be the subject of public notice and opportunity for comment in order to satisfy the applicable legal requirements.

C. HCFA Should Accept the PPRC's Recommendation

The Physician Payment Review Commission, which reviewed the HCFA proposal for drug payment limits in the context of the Administration's parallel legislative proposal, commented that, because physicians do not face uniform prices, "formulation of policy in this area is difficult." The Commission recommended that "alternative policies should be studied" instead of "putting an artificial limit on what physicians, who have little control or prices, can be reimbursed ...."[2/]

ASCO agrees with the Commission that the most appropriate course of action at this time is to defer adoption of a uniform payment methodology pending further study. The present basic methodology and carrier discretion should continue in the interim.

D. Considerations in Establishing A Realistic and Equitable Payment Method

As discussed above, we believe that any across-the-board methodology for all drugs would fail to conform to the statutory authority for limits only where the payments for "particular items or services" have been shown to be grossly excessive. We will nevertheless address the considerations that HCFA should take into account if it proceeds to establish a uniform payment methodology.

2/ Letter dated June 24, 1991, from Philip R. Lee, M.D., Chairman of the Commission, to the Speaker of the House of Representatives and the President of the Senate, pages 16-18.

1. Drug Acquisition Costs

Physicians can frequently purchase drugs for less than the published AWP. It is not clear, however, what amount of discount should be assumed to exist. The OIG surveys were poorly designed to address this question, since they dealt with a relatively small number of oral drugs purchased by pharmacies. The OIG surveys were also geographically limited, and the 1989 survey was mostly based on information from a single wholesaler. It is by no means clear that the results of these limited surveys adequately reflect prices paid by physicians for injectable drugs that are often relatively low volume products.

Whatever basic acquisition cost is assumed, however, it must be modified to take into account Medicare's payment policies. If Medicare pays only for the amount of drug actually used, there will inevitably be wastage of drug for which the physician is not reimbursed. The amount of the drug in a standard container size rarely corresponds exactly to the prescribed chemotherapy dosage for a patient, since prescribed dosages vary depending on the type of cancer involved and physical characteristics of each patient. Once a drug container is opened, good medical practice requires that the contents be used or disposed of in a limited period of time to assure sterility. For example, the labeling for etoposide -- one of the principal chemotherapy agents -- recommends disposal 48-96 hours after opening. Since the timing of chemotherapy obviously depends on the needs of the patients, it is sometimes impossible to use the left-over drugs before their sterility can no longer be assured. Such losses are compounded by the fact that a patient may be given up to three different types of drugs in one chemotherapy regimen, and the remainders of each are subject to wastage.

Also, despite best efforts, accidental breakage of drug containers occasionally occurs. In addition, drugs are sometimes not used before they expire, partially because, as noted, the needs of the patient dictate when a drug will be used.

Definitive data on drug wastage are not available, but it can be substantial. One large, multi-site oncology practice that carefully monitors drug wastage estimates that about 25 percent of the drugs it purchases are lost to waste and not billed. It is clear that this factor can be a major cost factor to oncology practices.

2. Other Drug-Related Costs

In determining a reasonable charge for drugs, and in determining a "realistic and equitable" payment limitation, HCFA should consider all costs directly related to use of the drugs. If certain costs are incurred only because drugs are administered in a physician's office, these costs should be covered by the Medicare payment for the drugs. Principal among these costs are certain administrative costs, sales tax in some states, and unpaid coinsurance.

There are administrative costs that are associated exclusively with use of drugs in a physician's office, such as procurement costs and costs of maintaining the inventory. In addition to personnel costs, these costs include the significant cost of capital (or debt service) to maintain an inventory of drugs that may be worth tens of thousands of dollars. Although it is difficult to

quantify these costs, some allowance must be made for them in calculating a reasonable Medicare payment amount if the payment amount is to cover all the costs associated with the drugs.

In some states, drugs administered by physicians are subject to the sales tax. Physicians who must pay that tax are obviously subjected to out-of-pocket losses if Medicare does not reimburse it.

An additional cost, which can be very significant, is unpaid coinsurance. Under Medicare Part B, patients must pay a 20 percent coinsurance payment each time they receive covered drugs. This coinsurance is sometimes uncollectible. Bad debt costs for oncologists can be substantial, especially for higher cost drugs. For example, the patient's share of a $500 chemotherapy regimen is $100.

Any payment method designed to cover the costs of drugs should take into account bad debts related to those drugs. Failure to do so would result in out-of-pocket losses for the physician. Consideration of bad debts in determining reasonable charges would be consistent with the payment methodology for maintenance dialysis, where bad debts are paid. 42 C.F.R. § 413.170(e). As in the case of dialysis, where bad debts are appropriately paid because the coinsurance requirement can be substantial, a prolonged course of chemotherapy can similarly result in a large patient liability and hence a large potential out-of-pocket loss to the physician when the coinsurance is not paid.

E. Adverse Effects of the Proposal

The analysis in the notice of proposed rulemaking of the potential impact of the proposal is extremely limited. The preamble asserts that "physicians are in an excellent position to demand discounts" because "drug sales are dependent upon the drugs a physician prescribes .... " Based on this assumption about physicians' market power, the notice concludes, "Since the physician has great leverage with the entity from which he or she purchases drugs to acquire a significant discount for the drug, we do not anticipate that there will be an adverse effect upon quality, access, beneficiary liability, assignment rates, reasonable charge reductions on unassigned claims, and participation rates of physicians." 56 Fed. Reg. 25801. ASCO disagrees with the premise that physicians have great leverage to obtain lower prices and with the conclusion that there will be no adverse effects from the proposed sharp reductions in payments.

The notion that physicians have leverage to demand price reductions because drug sales depend on physicians is faulty economic analysis. Sales of all products depend on customers' buying them, but that axiomatic fact does not mean that the buyers have great leverage over the sellers. To the contrary, buyers have market power only in limited circumstances, such as when they are of unusually large size. That is, of course, not the case for physicians, who typically purchase relatively small quantities of drugs. To the extent that the HCFA proposal relies on a belief that physicians will be able to obtain lower prices to offset Medicare's payment reductions, the proposal is seriously misguided. Physicians will face the same market conditions they do now, regardless of what Medicare's drug payment policy is. The developing experience with the recently enacted Medicaid rebate law indicates that even large purchasers, such as the Department

of Veterans Affairs, may lack the ability to demand deep discounts when the sellers decide that it is no longer in their interest to offer them lower prices.

The expectation that physicians may unilaterally demand discounts is particularly inappropriate in anticancer chemotherapy. Unlike a pharmacy, which buys a wide range of products from a number of different manufacturers with many drugs being substitutable for one another, an oncologist must have every available anticancer drug in his armamentarium or he may not be able to provide patients with state-of-the-art care. If an oncologist is placed in a position where he or she is required to forgo a particular product because of the unwillingness of the manufacturer to provide discounts, patient care will be at risk. Therefore, without jeopardizing the well-being of beneficiaries, it is difficult to see how HCFA could conclude that "physicians are in an excellent position to demand discounts." Physicians who wish to care properly for their patients simply do not have the bargaining power to threaten doing without a particular drug -- which is the only way to force the discounting contemplated by the proposed rule.

If physicians incur out-of-pocket losses on drugs that they administer, some may be compelled to cease purchasing drugs for their own inventory. Patients who need an injectable drug would be required to purchase it out of their own funds at a pharmacy and bring it to the physician's office for administration. This highly undesirable outcome would not only be a major inconvenience for patients (many of whom, like the patients of oncologists, are seriously ill), but it would also deprive the patients of Medicare coverage, since Medicare covers drugs only as an incident to a physician's service. Thus, to preclude the possibility of loss of Medicare coverage and a significant shift of drug costs to beneficiaries, it is essential that Medicare payment for drugs fully cover physicians' costs related to those drugs.

Another unintended consequence of the proposal may be to encourage the shifting of care from the relatively low cost physician's office to the more expensive hospital setting. A recent survey by the General Accounting Office found that a substantial number of oncologists admitted patients to a hospital because of the refusal of third-party payors to reimburse for outpatient administration of anticancer drugs.[3/] The systematic under-reimbursement of anticancer drugs could have the same impact. Thus, paradoxically, the proposal to reduce payments for drugs could actually result in higher cost to the program.

Finally, the experience with erythropoietin (EPO), recently analyzed in the Journal of the American Medical Association (JAMA),[4/] underscores the risk of inadequate payment for important pharmaceutical products. A team from the congressional Office of Technology Assessment reviewed the history of HCFA's reimbursement of EPO for dialysis patients during a period when payment per treatment was capped and concluded:

3/ "Off-Label Drugs: Initial Results of a National Survey," GAO/PEMD-91-12BR (February 1991).

4/ JAMA, July 10, 1991, Vol. 266, No. 2, p. 247.

> "Perhaps most important, the case of recombinant human erythropoietin emphasizes the importance of assessing the quality of care provided to beneficiaries. Given the strong financial incentive for providers to skimp on the dose, HCFA policy fell short in failing to establish mechanisms to routinely monitor dose and patient response. It now appears that, for thousands of beneficiaries, Medicare expenditures over many months were supporting ineffective doses, and patients were not reaping the full potential of recombinant human erythropoietin treatment."[5/]

The analogy between the EPO payment methodology and the proposed methodology for other drugs is not precise because the current proposal would not cap payment for each treatment in the same way, but the fact remains that both represent dramatic and unexplored deviations from past practice in payment for drugs. It is difficult to predict, and HCFA has apparently not even considered, the possible impact on patient care of adopting a payment methodology for anticancer chemotherapy drugs which in some states will drastically reduce the amounts physicians are reimbursed for these products.

F. Conclusion

In ASCO's view, HCFA should not implement the proposed reduction in payment for drugs. The proposed across-the-board methodology does not conform to the statutory requirement that payment limits be established only if charges would otherwise be grossly excessive for particular items or services. The current payment method should be continued while other approaches to drug payment are studied.

If HCFA is determined to adopt a uniform payment methodology, it should at least insure that the method meets the statutory requirement that the payments be "realistic and equitable." This means that the Medicare payment should be calculated to include the costs of drug product that is unavoidably wasted as well as administrative, sales tax, and bad debt costs directly related to drug use. While definitive data are not available to estimate acquisition cost, wastage amounts, administrative costs, sales tax, or bad debts, reasonable estimates suggest that a realistic and equitable payment amount would be substantially higher than the proposed 85 percent of AWP.

For example, if we assume 25 percent wastage (as suggested by the information discussed above), 15 percent bad debts, and 5 percent administrative costs (with sales tax varying from state to state), and if we assume that the OIG survey results are correct and applicable to drugs purchased by physicians, the estimated acquisition cost of 85 percent of AWP should be increased by 45 percent (to about 125 percent of AWP) to cover the assumed costs. Although ASCO recommends retaining current payment rules, if HCFA does plan to take action based on the very limited information it has available to it, the agency should be sure that all costs are reasonably covered.

5/ Id. at 252.

PAYMENT FOR ADMINISTRATION OF DRUGS

At present, Medicare generally pays a separate charge for administration of an injection (Medicare Carriers Manual, § 5202). The Manual specifies that the allowable charge should be $2, although some carriers may be paying a higher amount. Under HCFA's proposal, Medicare would no longer pay an injection administration fee if any other service (such as an office visit) was furnished at the same time as the injection.

In addition to the general codes for drug injections -- to which the Manual provision presumably applies -- the CPT establishes other codes for specialized types of injections. Among these are the codes for chemotherapy administration (CPT codes 96400-96549).

Under the proposal, HCFA would continue to pay a separate administration fee for those forms of chemotherapy considered to be procedures rather than injections. Thus, chemotherapy administered by infusion (CPT codes 96410, 96412, 96414, 96422, 96423, 96425) and the administration of chemotherapy into specialized body cavities (CPT codes 96440, 96445, 96450) would continue to be paid separately. However, there would no longer be a separate payment for chemotherapy administered intravenously by push technique (CPT codes 96408, 96420), or for subcutaneous or intramuscular injections of chemotherapy agents (CPT code 96400).

ASCO supports HCFA's recognition that a separate payment is generally appropriate for chemotherapy administration. Oncologists administering chemotherapeutic agents incur substantial practice costs beyond the overhead expenses of, for example, an internist's office. These extra costs include specialized equipment (such as special chairs for the patients undergoing chemotherapy and laminar flow hoods for mixing the chemotherapy agents), additional office space, specially trained oncology nurses, and special waste disposal costs. In addition, significant personnel time is needed for mixing and preparing the drugs and, especially in the case of infusions, for administering the drug. It would be totally inappropriate to regard these substantial drug administration costs as covered by the payment for an office visit, and HCFA properly proposes to continue the current practice of making a separate payment.

In our view, however, the proposal inappropriately excludes chemotherapy administered by push technique from this separate payment. It is true that injections by push take less time than injections by infusion, and the personnel cost is therefore reduced. The costs of chemotherapy administration by push, however, are in no way comparable to the costs of an ordinary intramuscular injection of a non-toxic drug, as the proposal seems to assume. Almost all of the costs incurred in connection with infusion injections are also present in the case of pushed injections, including the specialized equipment, nurses, and waste disposal. The only difference is the reduced time involved in the administration itself. The other costs remain substantial and would not properly be covered by assuming their inclusion in the office visit charge. Medicare should therefore continue to make a separate payment for chemotherapy injections by push technique (CPT codes 96408, 96420).

Medicare should also continue to pay separately for intramuscular or subcutaneous chemotherapy injections (CPT code 96400). Although not many chemotherapy drugs are administered in this fashion, these injections do involve additional overhead costs beyond the

costs incurred for non-toxic injections. For example, the common chemotherapy agent L-asparaginase is administered intramuscularly. This agent can require mixing, has significant potential side effects, and is subject to the special waste disposal requirements as other chemotherapy agents. Thus, HCFA should continue to pay separately for these types of chemotherapy injections.

Finally, we want to bring to HCFA's attention a potential problem in calculating the national average allowed charge for the chemotherapy administration codes. There is some variation in how the Medicare carriers use the codes where more than one chemotherapy agent is administered. Particularly in the case of pushed injections, some carriers allow reporting a code (e.g., 96408) for each drug used. This interpretation is consistent with advice given by the American Medical Association coding staff concerning pushed injections. Moreover, since multiple drugs result in greater overhead costs than a single drug, this coding method distinguishes the level of practice expenses incurred in various situations. The majority of Medicare carriers, however, require a code to be reported only once regardless of the number of drugs involved. Because the allowed charges in carrier areas where a code is reported for each drug can be significantly lower than in areas where the code is reported only once no matter how many drugs are used, it would not be appropriate simply to average all the allowed charges together. Charges should be adjusted before averaging so that they all represent the same service.

SUPPLIES

Oncologists use supplies extensively in connection with chemotherapy administration. These supplies include tubing and other equipment for intravenous injections, specialized needles, blood collection bottles, and other disposable items.

Under the proposed rules, Medicare would ordinarily not pay separately for supplies used in connection with physician services. Instead, supply costs would be considered covered by the practice expense component of the payment for physician services.

A. Allocation of Supply Payments

ASCO agrees in principle with the proposed approach of generally considering supply costs to be included in the payments for practice expenses. Thus, in the case of chemotherapy, it is reasonable for the chemotherapy administration codes to cover supply costs as well as the other expenses involved.

ASCO strongly opposes, however, the method by which HCFA is proposing to deal with supply costs in those carrier areas where supplies have traditionally been paid separately. The notice states that HCFA is considering allocating dollars currently paid for these supplies across practice expense relative values for all office-based procedures.

In our view, it would be highly unfair to allocate supply costs across all procedures. A number of carriers now pay separately for certain supplies ordinarily used in chemotherapy administration (e.g., infusion trays, intravenous tubes). Since these supplies are consistently used

in many chemotherapy administration procedures, ASCO does not object to a bundled payment that includes these supplies as well other technical aspects of the chemotherapy administration. Allocating current supply payments across all procedure codes, however, will dilute the impact of these costs and will thereby fail to establish a proper payment level for the bundled chemotherapy administration code.

Under the statute, the payment level for the chemotherapy administration codes will be based on national average allowed charges in 1991 for that service. Those carriers that have paid for chemotherapy supplies separately should bundle those supply costs into the chemotherapy administration charges in determining these amounts. Only in this manner will the payment amounts of the various carriers be comparable.

B. Separate Payment for Parenteral Hydration Products

The proposed regulation does not expressly discuss the proposed treatment of the fluids that are administered intravenously in connection with chemotherapy. These fluids are currently considered drugs for HCPCS coding purposes. We believe that most carriers pay for such fluids as drugs, although a few may treat them as supplies, for which they may or may not make separate payments.

Parenteral hydration fluids should be considered drugs and paid for in the same manner as other drugs, and we request that HCFA clarify this point in the final regulation. The use of fluids varies greatly depending on the type of chemotherapy used. Some drugs do not require hydration, while others necessitate the administration of substantial quantities of fluids. Because of this variability of an item of substantial cost, it would not be appropriate to bundle the costs in chemotherapy administration payments. Rather, separate payment should be made as in the case of any other drug.

C. Separate Payment for Certain Supplies

Certain supplies would be subject to separate payments under the proposal. These are identified in the notice as relatively expensive, disposable supplies used in connection with particular procedures (including lumbar puncture trays, venous access catheters, thoracentesis trays, and bone marrow aspiration trays, among others). These supplies would be paid separately only if they were used in a procedure that is routinely furnished in a hospital or ambulatory surgical center, as determined by HCFA. Payments for the supplies would be based on a nationally uniform fee schedule add-on.

ASCO supports this proposal to make separate payments for those supplies identified in the notice, and agrees that a nationally uniform payment amount is appropriate. However, it is important that the payment amount accurately reflect the actual costs of these supplies at any given time. HCFA apparently contemplates establishing the add-on payment at an amount exactly equal to the amount at which it believes the supplies can be purchased, as determined by surveys. We are concerned that the payment amount determined by these HCFA surveys will not necessarily reflect the actual supply costs faced by physicians due to price increases in supplies after the surveys are conducted. In order to adjust for these price increases, carriers should be

required to increase supply payments mid-year, if they determine that supply costs have increased.

MEDICAL VISITS AND CONSULTATIONS

ASCO supports HCFA's efforts to revise the visit and consultation codes in order to ensure uniform interpretation and allow for the use of appropriate relative values. We regret, however, that HCFA apparently plans to implement a series of new codes without affording an opportunity for public comment. Although we understand the time constraints involved, we urge HCFA to implement an appropriate notice and comment process that will allow full scrutiny of the new codes prior to their adoption.

ASCO is particularly concerned about the inclusion of time factors in the descriptors of the various visit codes. We believe that the time periods specified as being average for each level of service may not accurately reflect the actual time necessary for the oncology services involved. The lack of congruence between the content descriptors, which will actually govern the classification of services, and the supposedly average time period may provoke substantial controversy between carriers and physicians who perform the services more rapidly than the stated average time would suggest.

Although the definitions of the visit codes are far from complete, the early results confirm our concerns about use of the time factor. On January 23, 1991, the CPT Editorial Panel of the American Medical Association circulated to the CPT Advisory Committee its draft content descriptors, together with specialty-specific examples based on the vignettes and relative values determined by Hsiao. For example, the hematology/oncology vignette of "office visit for restaging of an established patient with new lymphadenopathy one year post therapy for lymphoma" was placed in level 5 (the highest level) of the series for established patients. Based on the content descriptor for level 5 and on the relative value for the vignette, this appears to be a correct classification. However, the estimated average face-to-face time for this level of service is stated to be 40 minutes -- a time period that would significantly exceed the time that an oncologist would ordinarily take to treat the patient described in the vignette.

Because the time estimates appear to be inaccurate, at least as they relate to the types of services performed by oncologists, ASCO urges HCFA not to include any time references in the content descriptors until they have been thoroughly verified and shown to be applicable to the kind of services performed by subspecialties such as medical oncology.

SERVICES FOR WHICH RELATIVE VALUES HAVE NOT BEEN ANNOUNCED

It is difficult to evaluate the impact on oncologists of the proposed fee schedule because it fails to set forth a relative value for most of the services performed by them. In addition to leaving unresolved the final form of the visit and consultation codes, the proposed fee schedule does not include proposed relative values for the chemotherapy administration codes (96400-96549) or for bone marrow aspiration (85095) -- procedures commonly performed by oncologists.

We assume that HCFA intends that the chemotherapy administration codes will be based only on practice expenses and malpractice costs and that the relative value for bone marrow aspiration will be developed in the Hsiao Phase III study. We urge HCFA to make available adequate documentation as to how it develops the fee schedule amounts for these codes to allow proper evaluation.

ASCO should have an opportunity to comment on these relative values and to have HCFA consider our comments in deciding on the final relative values. ASCO requests that HCFA make these important relative values known informally to ASCO as soon as possible, since they were not available for review during the public comment period. In addition, we agree with the statement in the proposal that such relative values should be interim in nature and subject to revision after a formal period of public comment.

MINOR SURGERY AND NONINCISIONAL PROCEDURES

The proposal contains new procedures for dealing with minor surgeries designated by a "star" in the CPT code book and with the "scopies" listed in the surgery section of CPT. In the case of the starred procedures, CPT instructs physicians to bill separately for the procedure and for any associated services or visits (i.e., a global charge is not used). CPT does not specify whether visit charges are appropriate in addition to "scopy" charges.

Under the HCFA proposal, no visit charge would generally be allowed in addition to the charge for the minor surgery or the "scopy" unless a documented, separately identifiable service is furnished. Also, the proposal would require the charge for the procedure to include all post-operative services "related to recovery from the procedure" for a period of 30 days. The minor surgeries and "scopies" that would be included in this policy would be identified in carrier instructions.

ASCO is concerned about this proposal. Some forms of chemotherapy require thoracentesis, paracentesis, or lumbar puncture (which are starred procedures) for their administration. As we understand HCFA's plans, HCFA will adopt a uniform national policy that the chemotherapy administration codes will represent practice expenses only and the physician's services associated with chemotherapy will be covered by a visit code (or a new chemotherapy management code). Thus, when the chemotherapy involves a thoracentesis, paracentesis, or lumbar puncture, there would ordinarily be a visit code accompanying that procedure code.

We believe that it would not be appropriate to require the submission of special documentation justifying the visit charge simply because a thoracentesis, paracentesis, or lumbar puncture was also part of the chemotherapy service furnished. A visit charge will typically accompany a chemotherapy administration charge and that visit charge should not become suspect simply because a lumbar puncture or similar procedure was part of the chemotherapy. Therefore, if HCFA implements this policy concerning visits and starred procedures, carrier instructions should specify that special documentation is not required for a visit charge accompanying a thoracentesis, paracentesis, or lumbar puncture if the procedure was part of chemotherapy administration.

ASCO also questions the proposal that all services "related to recovery" from a starred procedure and performed within 30 days would be considered included in the payment for the starred procedure. The test of what is "related to recovery" is not defined in the proposal except through a single example (removal of sutures). Although the example provided is clear, we believe that the issue of what is "related to recovery" may in many circumstances be much more ambiguous and subject to dispute. There does not seem to be good reason for departing from existing policy on charges for minor procedures, and ASCO urges that the proposed change not be adopted.

PROVIDER-BASED PHYSICIANS

ASCO supports the proposed termination of restrictions on payments to teaching physicians and other physicians who furnish services in hospitals, including the elimination of compensation-related customary charges. We agree with HCFA that Medicare payment for all physicians should be based on the fee schedule without additional limitations.